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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,011	06/04/2004	Jan Hall	21547/0286	9980

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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3774	

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06/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,011	HALL ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 4, filed 04/02/2009, with respect to restriction have been fully considered and are persuasive. The subject matter of claim 32 has been rejoined since "dental implant" is intended use defining no structure beyond the elected composition. Any dental structure that would be added to the claims will be withdrawn as nonelected as an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). Both the use of implant in the preamble and dental implant in the claim constitute intended use, but the elected product is still the implant material (stock material) set forth in the restriction dated 8/1/2007.

Applicant's arguments filed 04/02/2009 have been fully considered but they are not persuasive. The argument that Hunter et al (US 6447550) teaches away from highly porous is not persuasive. Column 4 lines 16-18 and lines 39-44 of Hunter et al clearly sets out the teaching of high porosity to promote ingrowth optimization of that porosity is a matter of routine experimentation which isn't patentably distinct from Hunter et al. Applicant is arguing from the stand point of use as a bearing element which is another embodiment. Regarding the use of pore as substance reservoirs, this is well known in the art and rejected below. Regarding the chemist comment, a chemist is not a limitation on to one of ordinary skill in the art in this application. Regarding the election of the Markush member, Applicant may provide equivalent alternative in a claim, but only one need be rejected (i.e. if one member of a Markush group is rejected, then no dependent claims to other member(s) are considered since the members as non-elected).

Double Patenting (held in abeyance, updated for the new claims)

Claims 33-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-9 of copending Application No. 10/482727 and Shimamune et al (US 4818572). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ only the substance TGF-β for which Shimamune et al (US 4818572) has the combination of CaP and TGF- β for bone ingrowth

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-5, 7 and 10 of copending Application No. 10/482737 and Shimamune et al (US 4818572). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ only the substance TGF-β for which Shimamune et al (US 4818572) has the combination of CaP and TGF- β for bone ingrowth.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33, 35, 37, 40, 43, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 6447550) in view of Baylink et al (US 5691305). Hunter et al discloses an implant (abs) comprising titanium and having one or more surfaces which can be applied in or on tissue areas and/or bone growth areas, one or more of the said surfaces being arranged with a depot (pores for osseointegration, col 4 lines 16-19 and 39-44), wherein the depot is formed by a pore arrangement in a relatively thick oxide layer on the titanium (3-7 and up to 10 microns thick of approx. 2 micron dia. grains forming pores in between, col 6-7, lines 66-17)., and wherein the oxide layer has a thickness in the range of 1-20 microns. However, Hunter et al remains silent as to including a TGF- β in the pores as a bone-growth-initiating substance or a bone-growth-stimulating substance. Baylink et al discloses another bone implant including a TGF- β (abs) in the pores as a bone-growth-initiating substance or a bone-growth-stimulating substance (claim 1) for promoting osseointegration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a TGF- β (abs) in the pores as taught by Baylink et al on the porous oxide layer of Hunter et al in order to promote osseointegration into the pores.

Regarding claim 35, Hunter et al does not expressly disclose with 1×10^7 - 1×10^{10} pores/cm^2. It has been held that it is not inventive to discover the optimum or workable ranges by routing experimentation and would be an obvious extension of the prior art teachings.

Regarding claims 40 and 46, the implant material disclosed is fully capable of use as a dental implant.

Claims 34, 36, 38-39, 41-42 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 6447550) in view of Baylink et al (US 5691305) as applied to claims 33 and 35 above and in further view of Larsson et al (US 6689170). Hunter et al discloses an implant as discussed above. However, Hunter et al remains silent as to the oxide layer has a surface roughness of about 1- 5 microns or less and that the oxide layer is highly porous, with pore diameters in the range of 0.01-10 microns. Larsson et al teaches another bone implant including the oxide layer has a surface roughness of about 1- 5 microns (col 15, lines 8-9) or less (submicron level) and that the oxide layer is highly porous, with pore diameters in the range of 0.01-10 microns (fig. 2a) for the purpose of promoting osseointegration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include pores in the side range surface roughness and volume as taught by Larsson et al in the porous oxide layer of Hunter et al in order to promote osseointegration. The total pore volume within the range of 0.05 and .00005 square centimeters is non elected as a member of the Markush group in claims 34 and 42 (i.e. the and/or does not require both).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774